K002964

DEC 1 9 2000

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (AS REQUIRED BY 21 CFR 807.92)

1. General Information

Device name:	Neuro II Intra-operative Imaging System
Trade name:	Neuro II
Common name:	MRDD (Magnetic Resonance Diagnostic Device)
Proprietary name:	Neuro II
Classification name:	System, Nuclear Magnetic Resonance Imaging
Classification:	21 CFR 892.1000
Class:	Class II
Product Code:	LNH (Magnetic Resonance Imaging System)

2. Indications for use

The IMRIS Neuro II MRI system is indicated for use for the head only.

3. Intended use of the device

The Neuro II is intended for use as a diagnostic patient imaging device. This device produces tomographic cross-sectional images that:

1. correspond to the distribution of protons exhibiting MR characteristics;
2. depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1) and spin-spin relaxation time (T2); and
3. display the soft tissue structure of the head.

When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

4. Device Description

The IMRIS Neuro II Intra-operative MRI system is a high resolution, head-only imaging system. The Neuro II system consists of a moveable 1.5 Tesla magnet and MR imaging system. The main components are the magnet assembly and magnet mover assembly (which includes an anti-collision system), the NMR electronics (which includes the operator console), the patient table assembly with the intra-operative head coil, skull clamp assembly, and the RF patient shield (only used in a non-shielded room). The Neuro II uses off-the-shelf imaging software.

5. Safety and Effectiveness

The use of the IMRIS Neuro II does not result in any additional potential hazards to safety issues such as static magnetic field effects, changing magnetic field effects, RF heating, or acoustic noise. Functional differences between the Picker Edge Eclipse system and the Neuro II system are minimal and have no impact on safety or effectiveness due to the backup safety features incorporated in the magnet mover assembly.

Use of an MR system in an operating room is not a new application for use, as the GE Signa Advantage SP Magnetic Resonance System is used intra-operatively also.

IMRIS has performed safety and quality testing in accordance with NEMA tests MS 1, 2, 3, 4, 5, 7, and 8.

It is the opinion of IMRIS that the Neuro II Intra-operative Magnetic Resonance Imaging System is substantially equivalent, based on IMRIS information provided with respect to the following legally marketed devices to which claiming equivalence.

Device	Manufactured by	FDA Classification #	510(k) #
Edge Eclipse 1.5T™ Magnet, NMR Electronics & VIA 2.0 Software	Picker International Inc. (Marconi Medical Systems)	892.1000	K964626
Skytron Model 3500 Table	Skytron	878.4960	K940616
MAYFIELD® Radiolucent Skull Clamp	OMI® Surgical Products	882.4460	K934289
Note: The General Electric (GE) Signa Advantage SP Magnetic Resonance System is also mentioned in our comparison due the intra-operative functionality of the GE system. The 510(k) # is K942604.			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2000

Innovative Magnetic Resonance Imaging Systems, Inc.
c/o Joel S. Faden
11605 Hitching Post Lane
Rockville, MD 20852

Re: K002964
Neuro II (Intra-Operative Magnetic Resonance Imaging System
Dated: September 21, 2000
Received: September 22, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Faden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K002964

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant:	Innovative Magnetic Resonance Imaging Systems Incorporated (IMRIS)
Device Name:	Neuro II Intra-operative Magnetic Resonance Imaging System

Indications For Use:

The IMRIS Neuro II MRI system is indicated for use for the head only.

The Neuro II is intended for use as a diagnostic patient imaging device. This device produces tomographic cross-sectional images that:

1. correspond to the distribution of protons exhibiting MR characteristics;
2. depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1) and spin-spin relaxation time (T2); and
3. display the soft tissue structure of the head.

When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

Prescription Use √
(Per 21 CFR 801.109)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002964

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)